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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,067	01/14/2004	Mohinder Singh	CU-3536 BSE	4134

26530 7590 05/11/2007  
LADAS & PARRY LLP  
224 SOUTH MICHIGAN AVENUE  
SUITE 1600  
CHICAGO, IL 60604

EXAMINER
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MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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05/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Art Unit: 1615

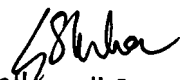
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit 1615

  
Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1600

# Office Action Summary

Application No.

10/757,067

Applicant(s)

SINGH, MOHINDER

Examiner

Snigdha Maewall

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 06/17/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Summary***

1. Receipt of IDS filed on 06/17/2004 is acknowledged.

Claims 1-16 are pending in this application and claims 1-16 will be prosecuted on the merits.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faust (US Patent No. 4,822,597) In view of Sixsmith (US patent No. 5,322,694).

Faust discloses a composition, which relates to chewing gum comprising anesthetics such as benzocaine, lidocaine etc which readily release the anesthetics such that it is available to anaesthise the throat and mouth areas, thereby providing relief to irritated areas. The amount of anesthetic that can be present is from about 0.05% to about 0.5%

(column 2, lines 5-10). The composition includes sweetener such as hydrogenated starch hydrolysate, sucralose and sugars like sucrose, glucose dextrose and fructose (column 4, lines 1-5 and lines 13-16). Flavoring agents such as mints, peppermint and spearmint can be added in the composition; artificial vanilla, cinnamon and kola extracts are shown to be added to the composition. Menthol oil, ginger oil and clove oil can also be added (column 4, lines 33-50).

Faust does not teach gelatin and silica in the composition. However, Sixsmith teaches gelatin and silica.

Sixsmith discloses a gelatin treated polyhydric alcohol compositions, their preparations to pharmaceutical lozenges (abstract). Local anesthetics that are used in the composition are benzocaine. The quantity of anesthetic required can vary widely and ranges from about 1-20 mg (column 5, lines 1-2). Excipients such as mannitol and colloidal silica are used in the composition (column 2, lines 5-9). The pharmaceutical dosage forms are used to treat conditions such as throat infections and thus inherently relieves pain.

Since the composition provided by Sixsmith comprising gelatin and silica helps in treating throat infections, it would have been obvious to the one of ordinary skilled in the art to incorporate gelatin and silica in the composition forwarded by Faust. A skilled artisan would have been motivated to make a formulation comprising benzocaine or any other anesthetic along with sucralose, sugars, hydrogenated starch hydrolysate and gelatin with a reasonable expectation of success. With respect to various percentage amounts of the various components in the

composition, it is the position of the examiner that such a parameter can be optimized with experimental manipulations. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

4. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faust (US Patent No. 4,822,597) In view of Sixsmith (US patent No. 5,322,694) and further in view of Mackles (US patent No. 4,260,596).

The teachings of Faust and Sixsmith have been discussed above.

Faust in combination with Sixsmith does not teach polyethylene glycol of between PEG-4 and PEG-800. However, Mackles discloses an edible unit dosage form capable of delivering liquid or soft gel product comprising benzocaine, mannitol, sorbitol, sugars and PEG-75 along with other excipients (abstract and column 3, lines 58-62). Since PEG 75 has been used effectively to produce an edible dosage form; it would have been obvious to one of ordinary skilled in the art at the time the invention was made to incorporate PEG-75 in the composition forwarded by Faust and Sixsmith. A skilled artisan would thus have been motivated to formulate a lozenge with PEG-75 along with other ingredients such as benzocaine, sugars, hydrogenated starch hydrolysate etc. as discussed above with a reasonable expectation of success.